

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



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JUN 18 2003

In re Application of: :  
Callens *et al.* :  
Serial No. 09/944,209 : Group Art Unit: 1623  
Filing Date: 09/04/2001 : Examiner: L. Maier  
For: Ureins Derived From  $\alpha,\omega$ - :  
Diaminoacids And Process For :  
Their Preparation :  
  
Mail Stop Appeal Brief - Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

APPELLANTS' BRIEF

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TABLE OF CONTENTS

	Page
I. THE REAL PARTY OF INTEREST .....	1
II. RELATED APPEALS AND INTERFERENCES.....	1
III. THE STATUS OF THE CLAIMS.....	1
IV. STATUS OF AMENDMENTS AFTER FINAL.....	2
V. SUMMARY OF THE INVENTION.....	2
VI. REFERENCE APPLIED AGAINST THE CLAIMS.....	2
VII. THE REJECTIONS APPEALED FROM .....	3
VIII. THE ISSUES ON APPEAL.....	3
IX. GROUPING OF THE CLAIMS.....	3
X. ARGUMENTS.....	3
XI. CONCLUSION.....	6
APPENDIX I .....	i



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**APPEAL BRIEF****I. THE REAL PARTY OF INTEREST**

Solvay S.A. is the real party of interest.

**II. RELATED APPEALS AND INTERFERENCES**

The undersigned is not aware of any related appeals or interferences involving this application.

**III. THE STATUS OF THE CLAIMS**

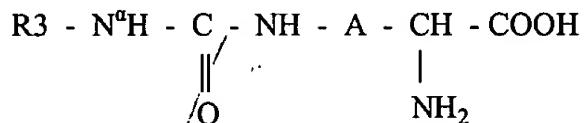
Claims 1-6, 8-10, 12, 13 and 16 have been cancelled. Claims 7, 11, 14, 15, 17-27 are pending which are attached in Appendix I. Claims 7, 18 and 22-27 are the only claims rejected and are the subject of this appeal.

**IV. STATUS OF AMENDMENTS AFTER FINAL**

There was one Amendment After Final filed February 10, 2003. The Amendment After Final was entered pursuant to an Advisory Action mailed March 6, 2003. The Examiner indicated that the § 102(b) rejection (based on Fung *et al.* U.S. Patent No. 5,032,577 has been overcome based on the reply. The Examiner indicated that the rejection based on 35 U.S.C. § 112, first paragraph, is maintained.

**V. SUMMARY OF THE INVENTION**

The invention is drawn to N<sup>ω</sup>-Carboxyalkylcarbamoyl- $\alpha$ , $\omega$ -diamino acids of general formula



in which A represents a bivalent group consisting of a linear carbon chain formed from 4 to 8 carbon atoms, which chain is optionally substituted by one or a number of groups chosen from C<sub>1</sub> - C<sub>3</sub> alkyl groups and functional groups comprising at least one oxygen or sulphur atom and in which R<sub>3</sub>-N<sup>α</sup>H represents an  $\alpha$ -amino acid and N<sup>α</sup> is a nitrogen atom attached to the  $\alpha$ -carbon of the  $\alpha$ -amino acid (see page 4, line 30-page 5, line 10).

**VI. REFERENCE APPLIED AGAINST THE CLAIMS**

There are currently no references applied against the claims.

**VII. THE REJECTIONS APPEALED FROM**

1. Claims 7, 18 and 22-27 were rejected under 35 U.S.C. § 112, first paragraph.

**VIII. THE ISSUES ON APPEAL**

1. Whether claims 7, 18 and 22-27 are rejectable under 35 U.S.C. § 112, first paragraph?

2. Whether the applicants have provided support for  $R^3-N^a$  H represents an  $\alpha$ -amino acid ...  $N^a$  is a nitrogen atom attached to the  $\alpha$ -carbon of the  $\alpha$ -amino acid is supported at pages 1 and 2 in the applicants' examples 1 and 2?

**IX. GROUPING OF THE CLAIMS**

Claims 7, 18 and 22 -27 are grouped together by the Examiner. These claims stand or fall together.

The Examiner has noted that claims 11, 14, 15 and 17 are allowed and claims 19-21 are objected to. These claims are not the subject of this appeal.

**X. ARGUMENTS**

Claims 7, 18 and 22-27 were rejected under 35 U.S.C. § 112, first paragraph. In particular, the Examiner stated five lines from the bottom of page 2 of the office Action,

[c]laim 7 has been amended to include the limitation "... in which  $R^3-N^a$  H represents an  $\alpha$ -amino acid... and  $N^a$  is a nitrogen atom attached to the  $\alpha$ -carbon of the  $\alpha$ -amino acid". It does not appear that there is support for this limitation in the specification. Applicant points to the paragraph bridging pages 1 and 2 and examples 1 and 2 to support this limitation.

However, this passage describes amino acids as broadly defined but does not support the limitation of all  $\alpha$ -amino acids.

The applicants respectfully disagree. The applicants again believe that there is support for this limitation bridging pages 1 and 2 and examples 1 and 2. In fact, additional support can be found in the specification at page 8, lines 23 and 24, which state,

"R3-NH is preferably an amino acid and more preferentially an essential amino acid". (emphasis added)

Clearly, this contemplates also amino acids other than essential amino acids as R3-NH group. In view of Examples 1 and 2, which disclose compounds in which R3-NH is an  $\alpha$ -amino acid with  $\text{N}\alpha$  being attached to the  $\alpha$ -carbon of the  $\alpha$ -amino acid, the limitation to any  $\alpha$ -amino acid clearly flows from the description at page 8, lines 24 to 25.

Again, the applicants do not have to have examples for all the possible  $\alpha$ -amino acids for the claims to be enabled (see In re Strahilevitz, 212 USPQ 561, 563, 564 (CCPA 1982), In re Stephens, 188 USPQ 659, 661 (CCPA 1976), In re Honns and Sims, 150 USPQ 652 (CCPA 1966), In re Marzocchi and Horton, 169 USPQ 367 (CCPA 1971)).

The court stated in re Stephens, *supra* at page 661,

The solicitor variously interprets 'specific embodiment' required by the rule as 'a complete example specifying all necessary details - including the essential materials, particle size where relevant and proportions, as well as the relevant specific parameters or conditions of the process and the essential physical characteristics of the product' and as a 'specific example' or what is commonly referred to as a working example. A working example, however, is not always necessary. In re Long, 54 CCPA 835, 368 F. 2d 892, 151 USPQ 640 (1966). ... The test is whether there is sufficient working procedure for one skilled in the art to

practice the claimed invention without undue experimentation.

In addition to the presence or absence of a working example, relevant considerations are the nature of the invention, the state of the prior art, and the relative skill of those in that art. In re Honn, 53 CCPA 1449, 364 F.2d 454, 150 USPQ 652 (1966). (emphasis added)

The Court of Custom Appeals stated at page 369 in re Marzocchi and Horton, 169 USPQ 367, 369 (CCPA 1971),

The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance. (emphasis added)

The Court of Custom Appeals stated at page 563 in re Strahilevitz, 212 USPQ 561, 563, 564 (CCPA 1982),

We recognize that working examples are **desirable** in complex technologies and that detailed examples can satisfy the statutory enablement requirement. Indeed, the inclusion of such examples here might well have avoided a lengthy and, no doubt, expensive appeal. Nevertheless, as acknowledged by the board, examples are not required to satisfy section 112, first paragraph rejection. (emphasis added)

In fact as discussed in the cases above, a patent application does not need to contain any examples for the application to be enabled. The applicants believe that it is clear from their specification, that there is adequate support and enablement for  $\alpha$ -amino acids.

The Court of Custom Appeals further stated at page 369 in In re Marzocchi and Horton, 169 USPQ 367, 369 (CCPA 1971),

As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. (In re Marzocchi and Horton, 169 USPQ 367, 369 (CCPA 1971). (emphasis added)

The applicants do not believe that there is any reason to doubt the objective truth of the statements presented in the application. For the above reasons, this rejection should be withdrawn.

#### **XI. CONCLUSION**

It is believed that the claims define an invention which is new, useful, and unobvious. For the above reasons, the applicants request passage to allowance. This brief is being submitted in triplicate. The PTO is authorized to charge Deposit Account No. 03-2775 the amount of \$320.00. The Notice of Appeal was filed on April 14, 2003. It is believed that no extensions are required.

However, in the event that the undersigned is mistaken in his calculations, an appropriate extension of time to respond is respectfully petitioned for, and the Commissioner is hereby authorized to charge the account of the undersigned attorneys, Patent Office Deposit Account No. 03-2775, for any fees which may be due upon the filing of this paper.

Respectfully submitted,

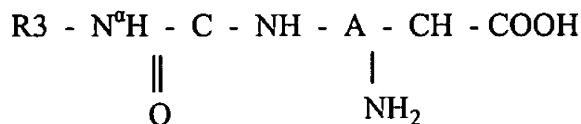
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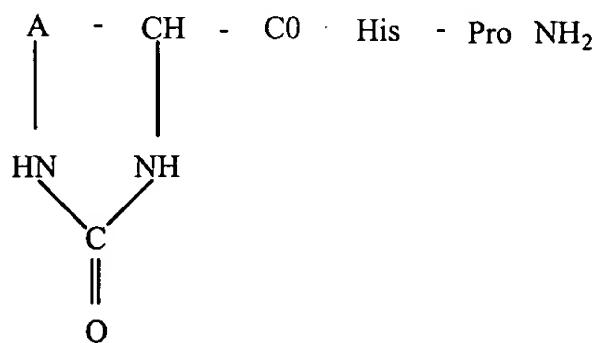
APPENDIX I

7.  $N^{\omega}\text{-Carboxyalkylcarbamoyl-}\alpha,\omega\text{-diamino acids of general formula}$



in which A represents a bivalent group consisting of a linear carbon chain formed from 4 to 8 carbon atoms, which chain is optionally substituted by one or a number of groups chosen from  $C_1 - C_3$  alkyl groups and functional groups comprising at least one oxygen or sulphur atom and in which  $R_3\text{-}N^aH$  represents an  $\alpha$ -amino acid and  $N^a$  is a nitrogen atom attached to the  $\alpha$ -carbon of the  $\alpha$ -amino acid.

11. A peptide of general formula



in which A is a bivalent group consisting of a linear carbon chain formed from 2 carbon atoms, which chain is substituted by at least one substituent selected from the group consisting of a functional group comprising at least one sulphur atom and a functional group comprising at least one oxygen atom selected from carboxyl, acyl, hydroxyl and alkoxy group.

14. The peptide according to claim 11, in which the linear carbon chain is substituted with a functional group containing sulphur.

15. The peptide according to claim 14, in which the functional group containing sulphur is a mercapto group.

17. The peptide according to Claim 11, wherein said functional group is selected from the group consisting of carboxyl, hydroxyl, alkoxy and mercapto group.

18.  $N^{\omega}$ -Carboxyalkylcarbamoyl- $\alpha,\omega$ -diamino acid as claimed in claim 7, wherein R3-N $^{\alpha}$ H- is an  $\alpha$ -amino acid.

19.  $N^{\omega}$ -Carboxyalkylcarbamoyl- $\alpha,\omega$ -diamino acid as claimed in claim 7, wherein R3-N $^{\alpha}$ H- is an essential  $\alpha$ -amino acid.

20.  $N^{\omega}$ -Carboxyalkylcarbamoyl- $\alpha,\omega$ -diamino acid as claimed in claim 7, wherein R3-N $^{\alpha}$ H- is tryptophane.

21.  $N^{\omega}$ -Carboxyalkylcarbamoyl- $\alpha,\omega$ -diamino acid as claimed in claim 7, wherein R3-N $^{\alpha}$ H- is methionine.

22.  $N^{\omega}$ -Carboxyalkylcarbamoyl- $\alpha,\omega$ -diamino acid as claimed in claim 7, wherein the linear carbon chain is substituted by a functional group comprising at least one oxygen atom.

23.  $N^{\omega}$ -Carboxyalkylcarbamoyl- $\alpha,\omega$ -diamino acid as claimed in claim 22, wherein, the functional group comprising at least one oxygen atom is selected from carboxyl, acyl, hydroxyl and alkoxy group.

24.  $N^{\omega}$ -Carboxyalkylcarbamoyl- $\alpha,\omega$ -diamino acid as claimed in claim 7, wherein the linear carbon chain is substituted with a functional group containing sulphur.

25.  $N^{\omega}$ -Carboxyalkylcarbamoyl- $\alpha,\omega$ -diamino acid as claimed in claim 24, wherein the functional group containing sulphur is a mercapto group.

26.  $N^{\omega}$ -Carboxyalkylcarbamoyl- $\alpha,\omega$ -diamino acid as claimed in claim 7, wherein the linear carbon chain is a polymethylene group.

27.  $N^{\omega}$ -Carboxyalkylcarbamoyl- $\alpha,\omega$ -diamino acid as claimed in claim 7, wherein said functional group is selected from the group consisting of carboxyl, hydroxyl, alkoxy and mercapto group.